PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

FENSTER, Paul
Fenster & Company Patent Attorneys, Ltd.
P.O. Box 10256
49002 Petach Tikva
ISRAËL

Date of mailing (day/month/year)
28 November 2000 (28.11.00)

Applicant's or agent's file reference
088/01050

IMPORTANT NOTIFICATION

International application No.
PCT/IL99/00284

International filing date (day/month/year)
30 May 1999 (30.05.99)

1. The following indications appeared on record concerning:

[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address
BY-PASS, INC.
40 Ramland Road
Orangeburg, NY 10962
Israel

State of Nationality: IL
State of Residence: IL
Telephone No.:
Facsimile No.:
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [ ] the name [X] the address [ ] the nationality [ ] the residence

Name and Address
BY-PASS, INC.
40 Ramland Road
Orangeburg, NY 10962
United States of America

State of Nationality: US
State of Residence: US
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:
THIS IS A CORRECTED VERSION.

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer
A. Karkachi

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

FENSTER, Paul
Fenster & Company Patent
Attorneys, Ltd.
P.O. Box 10256
49002 Petach Tikva
ISRAËL

Date of mailing (day/month/year)
28 November 2000 (28.11.00)

Applicant's or agent's file reference
088/01050

IMPORTANT NOTIFICATION

International application No.
PCT/IL99/00284

International filing date (day/month/year)
30 May 1999 (30.05.99)

1. The following indications appeared on record concerning:

[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address
BY-PASS, INC.
40 Ramland Road
Orangeburg, NY 10962
Israel

State of Nationality: IL
State of Residence: IL
Telephone No.:
Facsimile No.:
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [ ] the name [X] the address [ ] the nationality [ ] the residence

Name and Address
BY-PASS, INC.
40 Ramland Road
Orangeburg, NY 10962
United States of America

State of Nationality: US
State of Residence: US
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:
THIS IS A CORRECTED VERSION.

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

Authorized officer
A. Karkachi
Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 25 January 2000 (25.01.00)	
International application No. PCT/IL99/00284	**Applicant's or agent's file reference** 088/01050
International filing date (day/month/year) 30 May 1999 (30.05.99)	**Priority date** (day/month/year) 29 May 1998 (29.05.98)
Applicant DEROWE, Ari et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

27 December 1999 (27.12.99)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Juan Cruz

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF RECEIPT OF RECORD COPY

(PCT Rule 24.2(a))

To:

FENSTER, Paul
Fenster & Company
Patent Attorneys, Ltd.
P.O. Box 10256
Petach Tikva 49002
ISRAËL

Date of mailing (day/month/year)	**IMPORTANT NOTIFICATION**
01 July 1999 (01.07.99)	
Applicant's or agent's file reference	**International application No.**
088/01050	PCT/IL99/00284

The applicant is hereby notified that the International Bureau has received the record copy of the international application as detailed below.

Name(s) of the applicant(s) and State(s) for which they are applicants:

BY-PASS, LTD. (for all designated States except US)
DEROWE, Ari et al (for US)

International filing date	:	30 May 1999 (30.05.99)
Priority date(s) claimed	:	29 May 1998 (29.05.98) 19 March 1999 (19.03.99)
Date of receipt of the record copy by the International Bureau	:	14 June 1999 (14.06.99)
List of designated Offices	:	

AP :GH,GM,KE,LS,MW,SD,SL,SZ,UG,ZW
EA :AM,AZ,BY,KG,KZ,MD,RU,TJ,TM
EP :AT,BE,CH,CY,DE,DK,ES,FI,FR,GB,GR,IE,IT,LU,MC,NL,PT,SE
OA :BF,BJ,CF,CG,CI,CM,GA,GN,GW,ML,MR,NE,SN,TD,TG
National :AE,AL,AM,AT,AU,AZ,BA,BB,BG,BR,BY,CA,CH,CN,CU,CZ,DE,DK,EE,ES,FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KP,KR,KZ,LC,LK,LR,LS,LT,LU,LV,MD,MG,MK,MN,MW,MX,NO,NZ,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,UA,UG,US,UZ,VN,YU,ZA,ZW

ATTENTION

The applicant should carefully check the data appearing in this Notification. In case of any discrepancy between these data and the indications in the international application, the applicant should immediately inform the International Bureau.

In addition, the applicant's attention is drawn to the information contained in the Annex, relating to:

- [X] time limits for entry into the national phase
- [ ] confirmation of precautionary designations
- [X] requirements regarding priority documents

A copy of this Notification is being sent to the receiving Office and to the InternationalSearching Authority.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer:
R. Chrem

Telephone No. (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING
AMENDMENTS OF THE CLAIMS

(PCT Rule 62 and
Administrative Instructions, Section 417)

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C.20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as International Preliminary Examining Authority

Date of mailing (day/month/year)	
25 January 2000 (25.01.00)	
International application No.	International filing date (day/month/year)
PCT/IL99/00284	30 May 1999 (30.05.99)
Applicant	
BY-PASS, INC. et al	

The International Bureau hereby informs the International Preliminary Examining Authority that no amendments under Article 19 have been received by the International Bureau (Administrative Instructions, Section 417).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

Juan Cruz

Telephone No. (41-22) 338.83.38

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: MAIER FENSTER
FENSTER & COMPANY
PATENT ATTORNEYS, LTD.
POST OFFICE.BOX 10256
PETACH TIKVA 49002
ISRAEL

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing *(day/month/year)*	21 NOV2000

Applicant's or agent's file reference	IMPORTANT NOTIFICATION
088/01050	

International application No.	International filing date *(day/month/year)*	Priority Date *(day/month/year)*
PCT/IL99/00284	30 MAY 1999	29 MAY 1998

Applicant
BY-PASS, LTD.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	(JACKIE) TAN-UYEN THI HO
Facsimile No. (703) 305-3230	Telephone No. (703) 306-3421

Form PCT/IPEA/416 (July 1992)*

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: MAIER FENSTER
FENSTER & COMPANY PATENT ATTORNEYS, LTD.
POST OFFICE BOX 10256
PETACH TIKVA 49002
ISRAEL

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 088/01050	Date of Mailing *(day/month/year)* 09 NOV 1999
International application No. PCT/IL99/00284	FOR FURTHER ACTION See paragraphs 1 and 4 below
Applicant BY-PASS, LTD.	International filing date *(day/month/year)* 30 MAY 1999

1. [X] The applicant is hereby notified that the international search report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

[ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

[ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 *bis* 1 and 90 *bis* 3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer (JACKIE) TAN-UYEN THI HO
Facsimile No. (703) 305-3230	Telephone No. (703) 306-3421

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 088/01050	**FOR FURTHER ACTION**	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/IL99/00284	International filing date *(day/month/year)* 30 MAY 1999	(Earliest) Priority Date *(day/month/year)* 29 MAY 1998
Applicant BY-PASS, LTD.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. [ ] **Certain claims were found unsearchable** (See Box I).

2. [ ] **Unity of invention is lacking** (See Box II).

3. [ ] The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing
   - [ ] filed with the international application.
   - [ ] furnished by the applicant separately from the international application,
     - [ ] but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
   - [ ] transcribed by this Authority.

4. With regard to the **title**,
   - [X] the text is approved as submitted by the applicant.
   - [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,
   - [ ] the text is approved as submitted by the applicant.
   - [X] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is:
   Figure No. 4A
   - [ ] as suggested by the applicant.
   - [ ] because the applicant failed to suggest a figure.
   - [X] because this figure better characterizes the invention.
   - [ ] None of the figures.

International application No.
PCT/IL99/00284

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

NEW ABSTRACT

An anastomotic connector (60) for attaching two blood vessels, comprising a cylinder-like portion having a lumen, two ends, and an array of cells elements, and a tissue engaging portion (60) comprising at least one set of spikes (64) wherein at least one spike arranged adjacent one of the two ends of said cylinder-like portion. The connector (60) may comprise at least a second set of spikes (66) adjacent the other of the two ends.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

INTERNATIONAL SEARCH REPORT

ernational application No.
PCT/IL99/00284

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/56
US CL :606/153

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/153

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,695,504 A (GIFFORD, III et al.) 09 December 1997, Figs. 1-51, and cols. 13-69.	1-215
Y	US 5,234,447 A (KASTER et al.) 10 August 1993, Figs. 1-10, and cols. 4-6.	1-135
Y	US 5,366,462 A (KASTER et al.) 22 November 1994, Figs. 1-19, and cols. 4-6.	1-135
Y	US 5,368,736 A (KASTER) 18 January 1983, Figs. 1, 4-9, and cols. 6-11.	1-135

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search	Date of mailing of the international search report
07 OCTOBER 1999	09 NOV 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer (JACKIE) TAN-UYEN THI HO
Facsimile No. (703) 305-3230	Telephone No. (703) 306-3421

Form PCT/ISA/210 (second sheet)(July 1992)*

09701531
3713

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 088/01050	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IL99/00284	International filing date *(day/month/year)* 30 MAY 1999	Priority date *(day/month/year)* 29 MAY 1998
International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 17/56; and US Cl.: 606/153		
Applicant BY-PASS, LTD.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets.

   [✓] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 27 sheets.

3. This report contains indications relating to the following items:

   I [X] Basis of the report

   II [ ] Priority

   III [ ] Non-establishment of report with regard to novelty, inventive step or industrial applicability

   IV [ ] Lack of unity of invention

   V [X] Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   VI [ ] Certain documents cited

   VII [ ] Certain defects in the international application

   VIII [ ] Certain observations on the international application

Date of submission of the demand	Date of completion of this report
27 DECEMBER 1999	08 NOVEMBER 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer (JACKIE) TAN-UYEN THI HO Telephone No. (703) 306-3421

Form PCT/IPEA/409 (cover sheet) (July 1998)★

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/IL99/00284

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed

☒ the description:
pages (See Attached), as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:
pages (See Attached), as originally filed
pages _____, as amended (together with any statement) under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the drawings:
pages (See Attached), as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the sequence listing part of the description:
pages (See Attached), as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages NONE
☒ the claims, Nos. NONE
☒ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

***Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/IL99/00284

V. Reasoned statement under Article 35(2) with regard t n velty, inventive step r industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	1-158, 166-218	YES
	Claims	159-165	NO
Inventive Step (IS)	Claims	1-135, 143-158, 176-218	YES
	Claims	136-142, 159-175	NO
Industrial Applicability (IA)	Claims	1-218	YES
	Claims	NONE	NO

2. citations and explanations (Rule 70.7)

Claims 1-135, 143-158, and 176-218 meet the criteria set out in PCT Article 33(2)-(4) because the prior art does not teach or fairly suggest an anastomotic connector for attaching two blood vessels comprising a cylinder-like portion defining a lumen, having two ends and comprising an array of cells-elements; and a tissue engaging portion comprising at least one set of spikes comprising at least one spike arranged adjacent one of the two ends of said cylinder-like portion wherein said connector is adapted so the cylinder-like portion has no contact with blood flow when the connector is deployed; the prior art does not teach or fairly suggest a patch for sealing a hole in a blood vessel comprising a body which can be selectively collapsed or expanded, such that the patch fits inside a catheter having a diameter suitable for travel in said blood vessel; a plurality of tissue engaging elements on said patch; and a seal, wherein, when said device is expanded, placed over the hole, and the tissue engaging element engage said vessel, said seal seals said hole. The prior art also does not teach or fairly suggest a method of performing a bypass comprising the steps included in claims 182-215.

Claims 140-142 lack an inventive step under PCT Article 33(3) as being obvious over Kaster et al. (5,234,447). Kaster et al. disclose a graft having a side-to-end anastomic connector.
It would have been obvious to one having ordinary skill in the art at the time the invention was made to put Kaster et al.'s graft in a sterility-maintaining packaging in order to keep the graft sterile.

Claims 159-165 lack novelty under PCT Article 33(2) as being anticipated by Kaster et al. (5,234,447). Kaster et al. disclose a vessel holder, an expander (fig. 14-19, col. 6, lines 17-68).

Claims 166-175 lack an inventive step under PCT Article 33(3) (Continued on Supplemental Sheet.)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

I. BASIS OF REPORT:

This report has been drawn on the basis of the description,
page(s) 1-90, as originally filed.
page(s) NONE, filed with the demand.
and additional amendments:
NONE

This report has been drawn on the basis of the claims,
page(s) NONE, as originally filed.
page(s) NONE, as amended under Article 19.
page(s) NONE, filed with the demand.
and additional amendments:
Claim pages 91-114, filed with the letter of 21 September 2000.

This report has been drawn on the basis of the drawings,
page(s) 1-50, 52-63, 65-66, 68-69, as originally filed.
page(s) NONE, filed with the demand.
and additional amendments:
Pages 51, 64 and 67, filed with the letter of 21 September 2000

This report has been drawn on the basis of the sequence listing part of the description:
page(s) NONE, as originally filed.
pages(s) NONE, filed with the demand.
and additional amendments:
NONE

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):
as being obvious over Popov et al. in view of Shiber. Popov et al. disclose a tip mechanism for forming a hole in a blood vessel including all the limitations of the claims except for a presence of a motor coupled to said tip. Shiber discloses a cutting device comprising a motor coupled to a tip (fig. 1, col. 3, lines 58-68). It would have been obvious to one having ordinary skill in the art to use a motor for remotely controlling Popov et al.'s cutting tip.

Claims 136-139 lack an inventive step under PCT Article 33(3) as being obvious over Kaster et al. Kaster et al. disclose all the limitations of the claims except for a presence of an implantable device having a portion coated with a coagulation promoting material. It is a well known in the art to have an implantable device having at least a portion coated with a coagulation promoting material. It would have been obvious to one having ordinary skill in the art to coat a coagulation promoting material on a portion of Kaster's implantable device so that the coagulation promoting material coating would clot the blood and promote healing the surgical area.

---------- NEW CITATIONS ----------

US 5,041,082 A (Shiber) 20 Aug. 1991, see fig. 1, col. 3, lines 57-68
US 5,702,412 A (Popov et al.) 30 Dec. 1997, see fig. 3, col. 9 lines 1-68

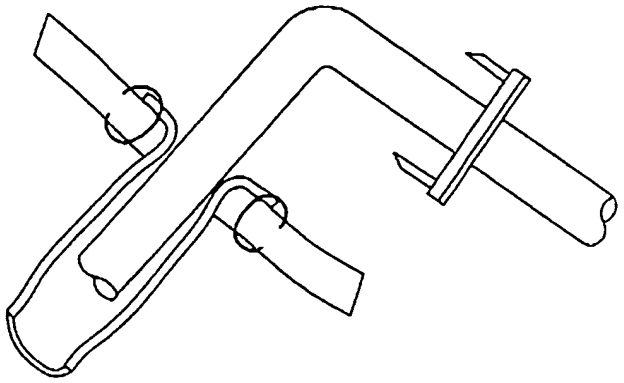

FIG.13C

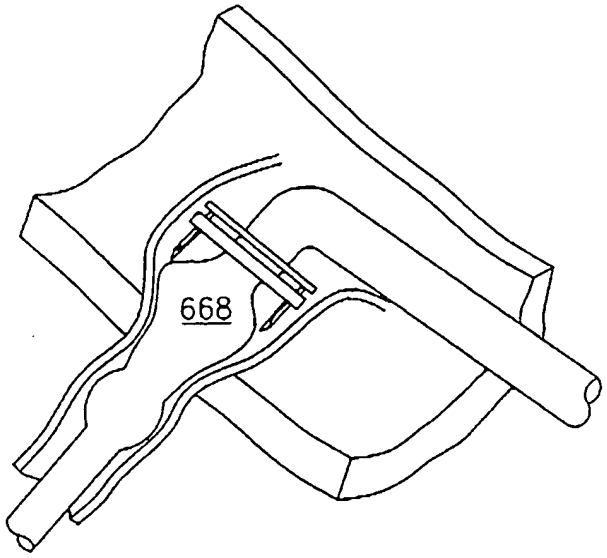

FIG.13D

CLAIMS

1. An anastomotic connector for attaching two blood vessels, comprising:

a cylinder-like portion defining a lumen, having two ends and comprising an array of cells-elements; and

a tissue engaging portion comprising at least one set of spikes comprising at least one spike arranged adjacent one of the two ends of said cylinder-like portion,

wherein said connector is adapted so the cylinder-like portion has no contact with blood flow when the connector is deployed.

2. A connector according to claim 1, comprising at least a second set of spikes adjacent the other of the two ends.

3. An anastomotic connector for attaching two blood vessels, comprising:

a cylinder-like portion defining a lumen; and

a plurality of tissue engaging portions for engaging two blood vessels, said plurality comprising at least one spike,

wherein radial expansion of said cylinder-like portion causes said at least one spike to engage tissue,

wherein said connector is adapted so the cylinder-like portion has no contact with blood flow when the connector is deployed.

4. An anastomotic connector according to claim 3, wherein radial expansion of said cylinder-like portion is de-coupled from axial contraction of said cylinder-like portion.

5. An anastomotic connector for attaching two blood vessels, comprising:

a cylinder-like portion defining a lumen; and

a plurality of tissue engaging portions for engaging two blood vessels,

wherein radial expansion of said cylinder-like portion is coupled to axial contraction of said cylinder-like portion,

wherein said connector is adapted so the cylinder-like portion has no contact with blood flow when the connector is deployed.

6. A connector according to claim 5, wherein at a maximum radial expansion, a ratio between axial contraction and radial expansion is more than about 1:10.

7. A connector according to claim 5, wherein at a maximum radial expansion, a ratio between axial contraction and radial expansion is between than about 1:10 and 1:5.

8. A connector according to claim 5, wherein at a maximum radial expansion, a ratio between axial contraction and radial expansion is between than about 1:5 and 1:2.

9. A connector according to claim 5, wherein at a maximum radial expansion, a ratio between axial contraction and radial expansion is between than about 1:2 and 1:1.

10. A connector according to claim 5, wherein at a maximum radial expansion, a ratio between axial contraction and radial expansion is between than about 1:1 and 2:1.

11. A connector according to claim 5, wherein at a maximum radial expansion, a ratio between axial contraction and radial expansion is between than about 2:1 and 4:1.

12. A connector according to claim 5, wherein at a maximum radial expansion, a ratio between axial contraction and radial expansion is less than about 4:1.

13. A connector according to claim 5, wherein said radial expansion activates at least one of said tissue engaging portions.

14. A connector according to claim 5, wherein at least one of said tissue engaging portions comprises at least one spike.

15. A connector according to claim 3, wherein said cylinder-like portion comprises a plurality of cell elements.

16. A connector according to claim 5, wherein said cylinder-like portion comprises a plurality of cell elements.

17. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said at least one spike is arranged to extend out of said lumen when said tissue engaging portions engage tissue in a completed anastomosis.

18. A connector according to claim 17, wherein said extended spike lies in a plane tangent to said cylinder-like portion.

19. A connector according to claim 17, wherein said extended spike lies in a plane perpendicular to said cylinder-like portion.

20. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said at least one spike is arranged to extend into said lumen when said tissue engaging portions engage tissue in a completed anastomosis.

21. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said device is arranged to cantilever said at least one spike into an extended configuration by an expansion of said cylinder-like portion.

22. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said device is arranged to release said at least one spike to assume an extended configuration by an expansion of said cylinder-like portion.

23. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein a portion of said cylinder-like portion is arranged to deform into said at least one spike, by an expansion of said cylinder-like portion.

24. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said spike is pre-stressed to lie outside of an axial profile of said cylinder-like portion.

25. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said spike is coupled to a base, and pivotally connected to said cylinder-like portion and wherein said base extends into said lumen.

26. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said cylinder-like portion includes a plurality of weakenings, such that plastically deforming said cylinder-like portion will extend said spikes to engage said tissue.

27. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said cylinder-like portion comprises a bi-stable cell, which cell extends said spike in one state and not in the other one of said states.

28. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said cylinder-like portion is arranged to twist, in at least one location thereon, which location is coupled to said at least one spike, whereby said twist causes said spike to extend.

29. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said spike comprises a protrusion to prevent transfixed tissue from slipping off said spike.

30. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said spike comprises a protrusion to prevent engaged tissue from slipping along said spike beyond said protrusion.

31. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said spike is arranged to bend at least 90° when it extends.

32. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said spike is arranged to bend at least 150° when it extends.

33. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said spike is arranged to bend at least 180° when it extends.

34. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said spike is arranged to bend at least 210° when it extends.

35. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said spike is arranged to bend at one point thereon when it extends.

36. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said spike is arranged to bend at at least two points th reon when it extends.

37. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said spike is arranged to bend in a continuous curve when it extends.

38. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said spike is arranged to engages said tissue when it is axially retracted relative to the cylinder-like portion.

39. A connector according to claim 38, wherein said at least one spike comprises a plurality of spikes and whercin each of said spikes is independently retractable.

40. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said at least one spike comprises at least two spikes and wherein said connector comprises at least a second spike and wherein said second spike is arranged to bend towards said at least one spike and said at least one spike is arranged to bend towards at least a second spike.

41. A connector according to claim 40, wherein spikes of said at least a second spike are arranged in a radially staggered configuration relative to said at least two spikes.

42. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said at least one spike is associated with an individual flat coil spring.

43. A connector according to ~~any of claims 2-4 or 14~~ claim 2, wherein said at least one spike is associated with an axial cell element, which cell element selectively retracts or extends said spike.

44. A connector according to claim 40, wherein spikes of said at least a second spike are arranged to be in a same plane as spikes of said at least one spike, when the spikes are in a bent configuration.

45. A device according to ~~any of claims 1-16,~~ claim 1 wherein said lumen has an elliptical cross-section.

46. A device according to ~~any of claims 1-16,~~ claim 1 wherein said lumen has a circular cross-section.

47. A device according to ~~any of claims 1-16,~~ claim 1 wherein said lumen has a polygonal cross-section.

48. A device according to ~~any of claims 1-16,~~ claim 1 wherein said lumen has fixed inner diameter.

49. A device according to ~~any of claims 1-16,~~ claim 1 wherein said lumen has a varying inner diameter.

50. A device according to claim 49, wherein said inner diameter has an hourglass profile, being flared at the ends of the lumen.

51. A device according to claim 49, wherein said lumen is flared at one end of the lumen.

52. A device according to ~~any of claims 1-16,~~ claim 1 wherein a cross-section of said lumen varies along said lumen.

53. A device according ~~to any of claims 1-16,~~ claim 1 wherein said lumen is matched to a coronary vessel.

54. A device according to claim 53, wherein said matching includes matching a degree of obliqueness of the lumen cross-section.

55. A device according ~~to any of claims 1, 2, 15 or 16,~~ claim 1 wherein at least one of said cell elements has parallelogram geometry.

56. A device according to ~~any of claims 1, 2, 15 or 16,~~ claim 1 wherein at least one of said cell elements has an elliptical geometry.

claim 1

57. A device according to ~~any of claims 1, 2, 15 or 16~~, wherein at least one of said cell elements comprises a ratchet for maintaining said cell element in a distorted configuration once such a configuration is achieved.

claim 1

58. A device according to ~~any of claims 1, 2, 15 or 16,~~ wherein at least one of said cell elements is arranged to distort out of a plane of said cell, when that cell is expanded along a certain axis thereof.

claim 1

59. A device according to ~~any of claims 1, 2, 15 or 16~~, wherein at least one of said cell elements comprises an outline geometrical shape.

claim 1

60. A device according to ~~any of claims 1, 2, 15 or 16,~~ wherein at least one of said cell elements comprises a substantially full geometrical shape.

claim 1

61. A device according to ~~any of claims 1, 2, 15 or 16,~~ wherein at least one of said cell elements is planar.

claim 1

62. A device according to ~~any of claims 1, 2, 15 or 16~~, wherein at least one of said cell elements is not planar.

claim 1

63. A device according to ~~any of claims 1, 2, 15 or 16,~~ wherein said cells are arranged as bands on at least a portion of said cylinder-like portion, each of said bands comprising substantially a single type of parallelogram.

64. A device according to claim 63, wherein said bands are axial bands.

65. A device according to claim 63, wherein said bands are circumferential bands.

claim 1

66. A device according to ~~any of claims 1, 2, 15 or 16,~~ wherein substantially all of said cylinder-like portions is composed of cell-elements.

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67. A device according to ~~any of claims 1, 2, 15 or 16~~ claim 1, wherein said cell elements meet at junctions and comprising at least one substantially rigid strut interconnecting at least two junctions.

68. A device according to ~~any of claims 1, 2, 15 or 16~~ claim 1, wherein said cell elements meet at junctions and comprising at least one substantially flexible wire interconnecting at least two junctions.

69. A device according to ~~any of claims 1, 2, 15 or 16~~ claim 1, wherein said cylinder-like portion comprises several cell types and wherein said cell types are uniformly distributed on said cylinder-like portion.

70. A device according to ~~any of claims 1, 2, 15 or 16~~ claim 1, wherein said cylinder-like portion comprises several cell types and wherein said cell types are non-uniformly distributed on said cylinder-like portion.

71. A device according to claim 70, wherein said distribution is symmetric.

72. A device according to claim 70, wherein said distribution is asymmetric.

73. A device according ~~to any of claims 1-16~~ claim 1, comprising one or more pressure protrusions on said cylinder-like portion, wherein said one or more pressure protrusions are arranged to increase a contact pressure between said two blood vessel when said device is deployed.

74. A device according to ~~any of claims 1-16~~ claim 1, wherein said cylinder-like portion comprises at least one part which is plastically deformable at a force which does not deform other parts of said portion.

75. A device according to claim 74, wherein at least one of said other parts reacts elastically at said force.

76. A device according to claim 74, wherein said part includes weakenings which guide the plastic distortion of said part.

AMENDED SHEET

77. A device according to ~~any of claims 1-16,~~ wherein said cylinder-like portion comprises at least one part which is super-elastic.

78. A device according to ~~any of claims 1-16,~~ wherein said cylinder-like portion comprises at least one part which comprises a temperature-triggered shape-memory material.

79. A device according to ~~any of claims 1-16~~, wherein said cylinder-like portion comprises at least one part which comprises a temperature-responsive bi-material composite, which changes its geometry under the effect of small temperature changes.

80. A device according to ~~any of claims 1-16~~, wherein at least one of tissue engagers comprises at least one part which is plastically deformable at a force which does not deform other parts of said tissue engagers.

81. A device according to claim 80, wherein at least one of said other parts reacts elastically at said force.

82. A device according to claim 80, wherein said part includes weakenings which guide the plastic distortion of said part.

83. A device according to ~~any of claims 1-16~~, wherein said at least one of tissue engagers comprises at least one part which is super-elastic.

84. A device according to ~~any of claims 1-16,~~ wherein said at least one of tissue engagers comprises at least one part which comprises a temperature-triggered shape-memory material.

85. A device according to ~~any of claims 1-16,~~ wherein said anastomotic connector is adapted to engage a side of one of said vessels and an end of another of said vessels, to perform a side-to-end anastomosis.

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86. A device according to claim 85, wherein said anastomosis is sealed by radial pressure exerted by said cylinder-like portion and wherein said tissue engagers maintain the cylinder-like portion in its position.

87. A device according to claim 85, wherein said tissue engagers maintain the relative positions of the two blood vessels.

88. A device according to claim 85, wherein said tissue-engaging portions are arranged on said cylinder-like portion such that when the anastomosis is complete, the cylinder like portion is at a certain angle perpendicular to the "side" vessel.

89. A device according to claim 85, wherein said certain angle is between about 70° and about 90°.

90. A device according to claim 85, wherein said certain angle is between about 50° and about 70°.

91. A device according to claim 85, wherein said certain angle is less than about 50°.

92. A device according to claim 85, wherein a cross-section of said lumen is matched to said certain angle.

93. A device according to ~~any of claims 1-16~~ CLAIM 1, wherein said anastomotic connector is adapted to engage an end of one of said vessels and an end of another of said vessels, to perform an end-to-end anastomosis.

94. A device according to claim 93, wherein said connector is adapted to be implanted outside of a vascular system.

95. A device according to ~~any of claims 1-16~~ CLAIM 1, wherein said anastomotic connector is adapted to engage a side of one of said vessels and a side of another of said vessels, to perform a side-to-side anastomosis.

96. A device according to claim 95, wherein said connector is adapted to be implanted outside of a vascular system.

97. A device according to ~~any of claims 1-16~~ claim 1, wherein said device is composed, at least in part, of a bio-absorbable material.

98. A device according to claim 97, wherein said cylinder-like portion is composed wholly of a bio-absorbable material.

99. A device according to claim 97, wherein at least one of said tissue engaging portions is composed wholly of a bio-absorbable material.

100. A device according to ~~any of claims 1-16~~ claim 1, wherein at least one of said tissue engagers is adapted to engage an everted graft.

101. A device according to ~~any of claims 1-16~~ claim 1, wherein at least one of said tissue engagers is adapted to engage a non-everted graft.

102. A device according to ~~any of claims 1-16~~ claim 1, wherein at least one of said tissue engagers is adapted to both an everted and a non-everted graft.

103. A device according to ~~any of claims 1-16~~ claim 1, wherein all of said tissue engagers are adapted to engage said blood vessels inside a body.

104. A device according to ~~any of claims 1-16~~ claim 1, wherein said cylinder-like portion has an axial dimension of about 0.5 millimeters.

105. A device according to ~~any of claims 1-16~~ claim 1, wherein said cylinder-like portion has an axial dimension of between about 0.5 millimeters and 2 millimeters.

106. A device according to ~~any of claims 1-16~~ claim 1, wherein said cylinder-like portion has an axial dimension of between about 2 millimeters and 5 millimeters.

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claim 1

107. A device according to ~~any of claims 1-16~~, wherein said cylinder-like portion has an axial dimension of between about 5 millimeters and 8 millimeters.

claim 1

108. A device according to ~~any of claims 1-16~~, wherein said cylinder-like portion has a ratio of about 1:1 between its axial dimension and its diameter.

claim 1

109. A device according to ~~any of claims 1-16~~, wherein said cylinder-like portion has a ratio of between about 1:1 and about 1:2 between its axial dimension and its diameter.

claim 1

110. A device according to ~~any of claims 1-16~~, wherein said cylinder-like portion has a ratio of between about 1:2 about 1:4 between its axial dimension and its diameter.

claim 1

111. A device according to ~~any of claims 1-16,~~ wherein said cylinder-like portion has a ratio of between about 1:4 about 1:8 between its axial dimension and its diameter.

claim 1

112. A device according to ~~any of claims 1-16,~~ wherein said cylinder-like portion is arranged to expand radially by a factor of less than about 1.5.

claim 1

113. A device according to ~~any of claims 1-16,~~ wherein said cylinder-like portion is arranged to expand radially by a factor of between 2 and 4.

claim 1

114. A device according to ~~any of claims 1-16~~, wherein said cylinder-like portion is arranged to expand radially by a factor of between 4 and 8.

115. An anastomotic connector for attaching two blood vessels, comprising:

a cylinder-like portion defining a lumen; and

a plurality of tissue engaging portions for engaging the blood vessels, said plurality comprising at least two spikes,

wherein said two spikes extend differently to engage said tissue,

wherein said connector is self-expanding.

116. A connector according to claim 115, wherein said spikes bend differently.

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117. A connector according to claim 115, wherein said spikes engage the same blood vessel.

118. A connector according to claim 115, wherein said spikes engage different blood vessels.

119. A connector according to claim 115, wherein said two spikes are arranged to extend simultaneously.

120. A connector according to claim 115, wherein said two spikes are arranged to extend sequentially.

121. A connector according to claim 115, wherein said two spikes are arranged to extend semi-sequentially, such that there is an overlap between their motion.

122. A connector according to claim 115, wherein said two spikes are extended by a same distortion of said cylinder-like portion.

123. A connector according to claim 115, wherein the extension of at least one of said spikes is decoupled from distortion of said cylinder-like portion.

124. A connector according to claim 115, wherein said two spikes are extended by different degrees of radial expansion of said cylinder-like portion.

125. A connector according to claim 115, wherein said extension comprises impaling a portion of a blood vessel.

126. A connector according to claim 115, wherein said extension comprises transfixing a portion of a blood vessel.

127. A connector according to claim 115, wherein said extension comprises pinching a portion of a blood vessel.

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128. An anastomotic connector for attaching two blood vessels, comprising:

a cylinder-lik portion defining a lumen; and

a plurality of tissue engaging portions for engaging the two blood vessels,

wherein said connector has at least two configurations, a first c nfiguration in which said tissue engaging portions are at a first extension stat and a second configuration wherein said tissue engaging portions are at a second extension state, wherein said connector exhibits a bi-modal behavior in changing from said first configuration to said second configuration.

wherein said connector is adapted so the cylinder-like portion has no contact with blood flow when the connector is deployed.

129. A connector according to claim 128, wherein said configuration change is effected by expanding said cylinder-like portion.

130. A connector according to claim 128, wherein said configuration change comprises the extension of a plurality spikes.

131. A connector according to claim 128, comprising at least one bi-stable element that controls said configuration change.

132. A connector according to claim 128, comprising at least one restraining element that controls said configuration change.

133. An anastomotic connector for attaching two blood vessel, comprising:

a cylinder-like portion defining a lumen; and

a plurality of tissue engaging portions for engaging the two blood vessels,

wherein said connector has at least two configurations, a first configuration in which said tissue engaging portions form a single vessel piercing tip and a second configuration wherein said tissue engaging portions are operative to engage tissue.

134. A connector according to claim 133, wherein said plurality of tissue engaging portions comprise at least one spike.

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135. A connector according to claim 133, wherein said plurality of tissue engaging portions are arranged at one end of said cylinder-like portions and comprising a second plurality of tissue engaging portions adjacent the other end of said cylinder-like portion.

136. An implantable device comprising:
a first portion designed to come in contact with blood; and
a second portion designed not to come in contact with blood,
wherein said second portion is coated with a coagulation-promoting material.

137. A device according to claim 136, wherein said device is an anastomosis connector.

138. A device according to claim 136, wherein said device is a vascular device for sealing a hole in a blood vessel.

139. A device according to any of claims 136-138, wherein said first portion is coated with a coagulation-retarding material.

140. A graft kit, comprising:
a sterility-maintaining packaging; and
a graft having at least two ends and having a side-to-end anastomotic connector attached to at least one of said two ends, wherein said anastomotic connector includes spikes for engaging a blood vessel.

141. A kit according to claim 140, comprising a restrainer for maintaining said spikes in an unengaged configuration.

142. A graft comprising:
a tubular body having at least one intersection, such that said body has at least three ends; and
at least two end-to-side anastomotic connectors attached to at least two of said three ends.

143. A hole puncher, adapted for punching a hole in a blood vessel, comprising:

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an outer tube having distal portion, which distal portion has a lip;

a punch element having a sharp tip suitable for penetrating a blood vessel and defining a depression distal from the tip, wherein said depression is of a size adapted to receive a blood vessel such that a substantially blood-proof seal is formed between the vessel and the depression,

wherein said distal portion of said outer tube has an outer diameter which is substantially the same as an outer diameter of said punch element and wherein said punch element fits snugly in said distal portion such that said lip can sever blood vessel tissue contained in said depression from tissue outside said depression.

144. A hole puncher according to claim 143, wherein said depression is distanced from said tip so that said distance is at least the thickness of the blood vessel.

145. A puncher according to claim 143, wherein said puncher is flexible enough to be provided through a blood vessel in which a hole is to be punched.

146. A puncher according to claim 143, comprising a handle.

147. A puncher according to claim 146, comprising means for advancing said outer tube relative to said handle and relative to said punch element.

148. A puncher according to claim 146, comprising means for retracting said punch element relative to said handle and relative to said outer tube.

149. A puncher according to ~~any of claims 143-148~~ claim 143, comprising means for advancing a graft into said hole formed by said punch.

150. A puncher according to ~~any of claims 143-148~~ claim 143, comprising a valve for preventing blood from leaking out of said outer tube once said punch element is removed.

151. A puncher according to ~~any of claims 143-148~~ claim 143, wherein said distal end comprises a stop for preventing entry of said distal end into said hole beyond said stop.

152. A puncher according to claim 151, wherein said stop is at an oblique angle relative to a main axis of said distal end, to guide said hole puncher to form an oblique punch.

claim 143 112 rack

153. A puncher according to ~~any of claims 143-148~~, c mprising a stop for preventing advance of said punch element relative to said distal end, beyond a pre-defined distance.

claim 143 112 1ST

154. A puncher according to ~~any of claims 143-148~~, wherein said punch element is radially expandable from a first, small diameter to a second, working diameter.

claim 143 112 rack

155. A puncher according to ~~any of claims 143-148~~, wherein said distal end is radially expandable from a first, small diameter to a second, working diameter.

claim 143

156. A puncher according to ~~any of claims 143-148~~, wherein said depression in said punch element is at an oblique angle relative to a main axis of said punch element, whereby an oblique hole is punched thereby.

claim 143

157. A puncher according to ~~any of claims 143-148~~, wherein said lip of said outer tube is at an oblique angle relative to a main axis of said outer tube, whereby an oblique hole is punched thereby.

claim 143 112

158. A puncher according to ~~any of claims 143-148~~, wherein said hole puncher is arranged to punch an oblong hole.

159. Apparatus for everting a vessel over an anastomotic connector, comprising:

a vessel holder for holding said vessel; and

an expander, adapted to engage said vessel, at least at an end of said expander, which end of said expander expands from a diameter of less than a diameter of said vessel to a diameter greater than that of said vessel and wherein in said expanded diameter, said at least said portion can enclose at least a portion of said vessel holder

160. Apparatus according to claim 159, comprising means for selectively moving said expander relative to said vessel, such that said engaged portion overlaps said vessel holder.

161. Apparatus according to claim 159, comprising a holder for an anastomotic connector.

162. Apparatus according to claim 161, comprising a retainer for maintaining said anastomotic connector in a desired configuration during at least a portion of said eversion.

163. Apparatus according to claim 159, wherein said apparatus is separable into two pieces.

164. Apparatus according to claim 159, comprising a guide for maintaining coaxiallity between said vessel holder and said expander.

165. Apparatus according to claim 164, wherein said guide comprises an intra-lumen vessel engager for engaging said vessel.

166. A tip mechanism for forming a hole in a blood vessel, from inside the blood vessel, comprising:

a wire portion;

a tip coupled to said wire portion; and

a motor coupled to said tip and adjacent to said tip.

167. A mechanism according to claim 166, wherein said wire is at least 10 cm long.

168. A mechanism according to claim 166, wherein said tip is a sharp tip.

169. A mechanism according to claim 166, wherein said motor is a piezoelectric motor.

170. A mechanism according to claim 166, wherein said motor is a magneto-strictive motor.

171. A mechanism according to claim 166, wherein said motor moves said tip in a rotational motion around a main axis of said wire.

172. A mechanism according to claim 166, wherein said motor moves said tip in an axial motion along a main axis of said wire.

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173. A mechanism according to any of claims 166-172, wherein said tip is smooth.

174. A mechanism according to any of claims 166-172, wherein said tip includes protrusions for engaging soft tissue.

175. A mechanism according to any of claims 166-172, wherein said tip has a geometry matched to a geometry of said motor, such that an amplitude of motion of said tip is at least twice the amplitude of said motor.

176. A patch for sealing a hole in a blood vessel, comprising:

a body which can be selectively collapsed or expanded, such that the patch fits inside an catheter having a diameter suitable for travel in said blood vessel;

a plurality of tissue engaging elements on said patch; and

a seal,

wherein, when said device is expanded, placed over the hole and the tissue engaging elements engage said vessel, said seal seals said hole.

177. A framework for an endoscopic procedure, comprising:

a body which can be selectively collapsed or expanded, such that it fits through a tube used to access a surgical area;

fixation members for attaching said body to tissue at said surgical area; and

guidance members for guiding one or more tools at said area to perform said endoscopic procedure,

wherein said body is operative not to be rigidly coupled to said tube while in a surgical area.

178. A framework according to claim 177, wherein said framework has a plurality of stable configurations and wherein said stable configurations are matched to a particular endoscopic procedure.

179. A framework according to claim 178, wherein said configurations are achieved by selectively inflating at least one balloon coupled to said framework.

AMENDED SHEET

180. A framework according to claim 177, comprising a safety line for attaching said framework to a tool which exits said body.

181. A framework according to claim 177, wherein said body is unattached to said tube.

182. A method of performing a bypass, comprising:

transvascularly providing a graft at a first location in a vascular system;

forming a hole at said location;

expelling at least most of said graft out of said hole;

navigating said graft adjacent a second hole in said vascular system;

forming a hole at said second location;

percutaneously performing a first independently patent anastomosis at said first location, which anastomosis does not occlude said vascular system at said first location; and

percutaneously performing a second independently patent anastomosis at said second location, which anastomosis does not occlude said vascular system at said second location.

183. A method according to claim 182, wherein at least one of said first and said second anastomotic connections is performed such that no portion of an anastomotic connector remains in contact with blood in said vascular system.

184. A method according to claim 182, wherein at least one of said first and said second anastomotic connections is a side-to-side anastomosis.

185. A method according to claim 182, wherein at least one of said first and said second anastomotic connections is a side-to-end anastomosis.

186. A method according to claim 182, wherein at least one of said first and said second anastomotic connections is an intima-to-intima anastomosis.

187. A method according to claim 182, wherein at least one of said first and said second anastomotic connections is an anastomosis between an intima and a inside of a vessel wall.

188. A method according to claim 182, wherein at least most of a graft comprises all of the graft.

189. A method according to claim 182, wherein at least most of a graft comprises all of the graft except for a lip thereof.

190. A method according to claim 189, wherein only an intima of said lip is exposed to blood in said vascular system.

191. A method according to claim 182, wherein expelling at least most of a graft comprises expelling all of the graft out of the lumen of said vessel while maintaining a portion of said graft in a cross-section of sad vessel wall.

192. A method of performing an anastomosis, comprising:

transvascularly providing a graft at a location in a vascular system;

forming a hole at said location;

expelling said graft completely out of said hole; and

transvascularly performing an independently patent anastomosis at said location, which anastomosis does not occlude said vascular system at said location.

193. A method according to claim 192, wherein said anastomosis is a side-to-end anastomosis.

194. A method according to claim 192, wherein said anastomosis is an end-to-end anastomosis.

195. A method according to claim 192, wherein said anastomosis is performed using an anastomotic connector and wherein said connector is completely outside a blood flow of said vascular system after said anastomosis.

196. A method according to claim 192, wherein said anastomosis is performed using an anastomotic connector and wherein said only spike portions of said connector are in contact with a blood flow of said vascular system after said anastomosis.

197. A method according to claim 192, wherein said anastomosis is performed using an anastomotic connector and wherein said connector forms said hole.

198. A method of anastomosis comprising:

providing an expandable anastomotic device across a blood vessel wall; and

inflating said device to simultaneously open an anastomotic passage and perform an anastomotic connection.

199. A method of anastomosis attachment comprising:

inserting an anastomotic device to attach two blood vessels; and

inflating a balloon in said device if said attachment leaks.

200. A method of punching a hole in a blood vessel, comprising:

providing a hole puncher to a location in a vascular system, which location has blood flowing therethrough;

transfixing a wall of said vascular system at said location;

removing a portion of said wall using said hole puncher, while said hole-puncher remains transfixing said wall; and

transporting a tool across said wall through a lumen of said hole puncher.

201. A method according to claim 200, wherein said removing comprises partially retracting a portion of said hole puncher.

202. A method according to claim 200, wherein said removing comprises partially advancing a portion of said hole puncher.

203. A method according to claim 200, comprising using said tool to perform an anastomosis connection.

204. A method according to claim 200 ~~any of claims 200-203~~, wherein said providing is from inside of said vascular system.

AMENDED SHEET

CLAIM 200

205. A method according to ~~any of claims 200-203~~, wherein said providing is from outside of said vascular system.

206. A method of everting a graft over an anastomotic connector, comprising:

sliding said anastomotic connector over said vessel, to a point adjacent an end of the vessel;

expanding a portion of said vessel between said point and said end; and

everting said expanded portion over said connector.

207. A method according to claim 206, wherein said everting and said expanding use a same tool.

208. A method according to claim 206, comprising transfixing said vessel at or about said portion with an anastomotic connector.

209. A method of performing a side to end anastomosis, comprising:

providing a graft to a location on a side of a blood vessel;

forming a hole in said side blood vessel;

engaging one surface of said side of the blood vessel, using a self expanding anastomosis connector to perform a first portion of the anastomosis; and

completing the anastomosis by engaging the second surface of said side using the anastomosis connector after said engaging one surface.

210. A method according to claim 209, wherein said providing is from inside of said blood vessel.

211. A method according to claim 209, wherein said providing is from outside of said blood vessel.

212. A method of performing a bypass procedure, comprising:

transvascularly providing a graft at a first location in a vascular system;

expelling at least most of said graft out of a hole at said first location;

navigating an end of said graft to a second location in said vascular system;

performing an anastomosis at said second locati n; and

thereafter transfixing said graft to said vascular system at said first location, using an anastomotic connector.

213. A method of performing an anastomosis, comprising:

providing a graft at a location in a vascular system;

forming a hole at said location; and

simultaneously expanding said hole and completing an anastomotic connection between said graft and said vascular system at said location.

214. A method according to claim 213, wherein said forming and said expanding comprises a continuous process.

215. A method according to claim 213, wherein said forming and said expanding comprises a discrete-step process.

216. A connector according to claim 30, wherein said protrusion and said spike have the shape of a fork.

217. A connector according to claim 3 ~~or claim 5~~, wherein said cylinder-like portion has a non-solid surface.

218. A connector according to ~~any of claims 1-16~~ claim 1, wherein at least 90% of a surface area of said connector is not in contact with the blood flow.

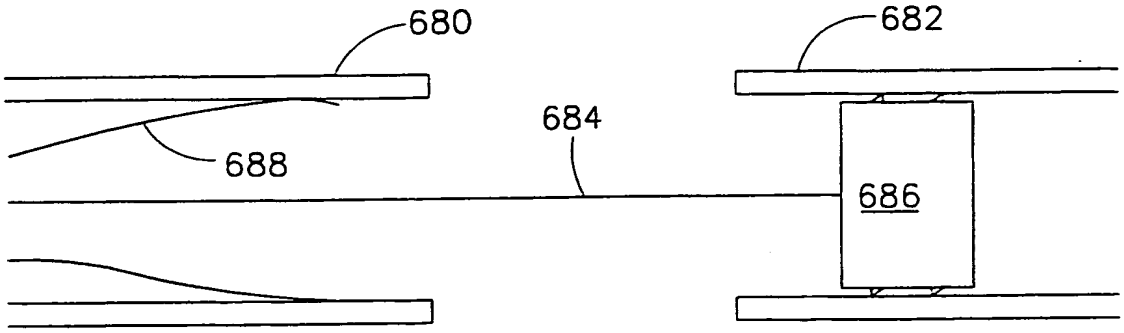

FIG.10E

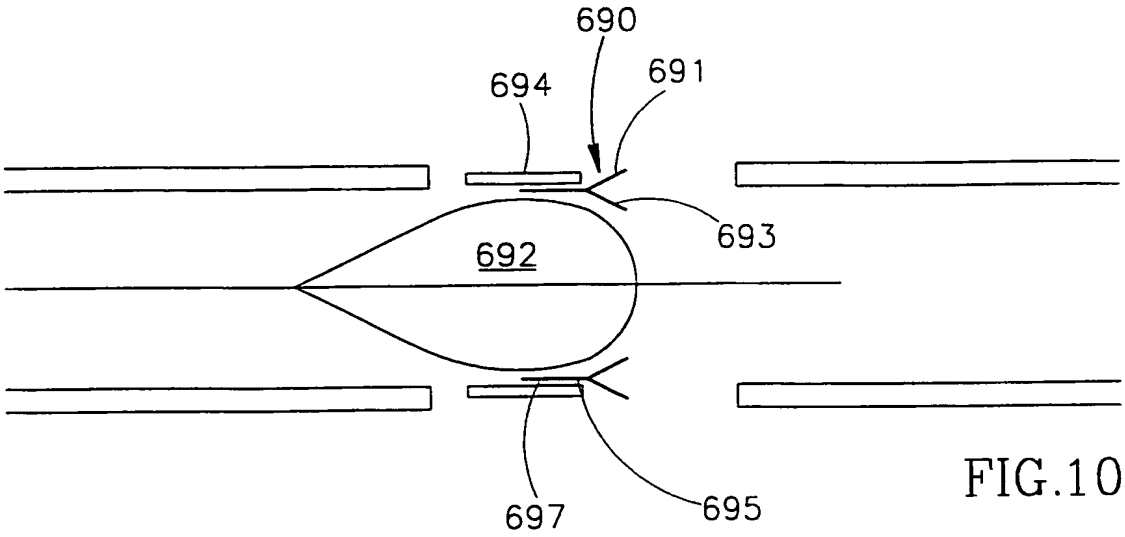

FIG.10F

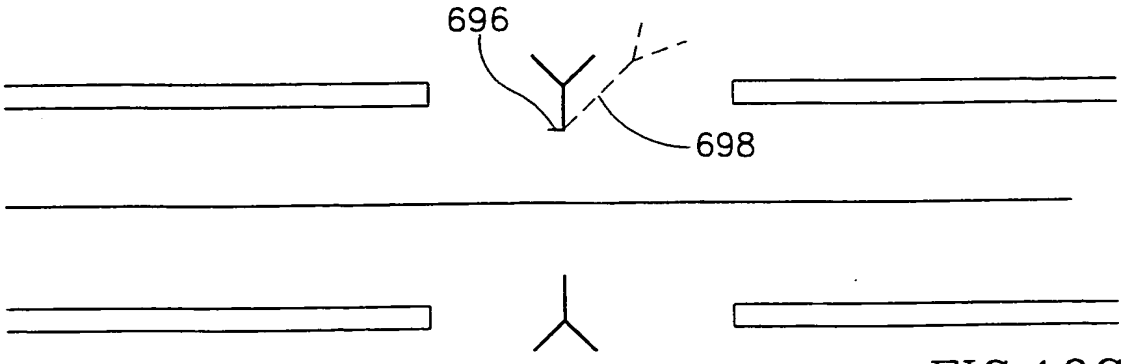

FIG.10G

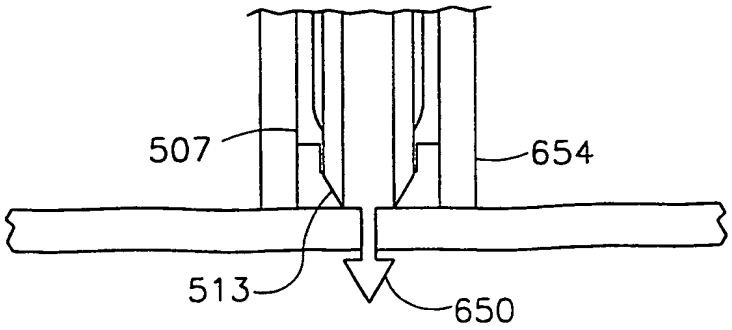

FIG.12Q

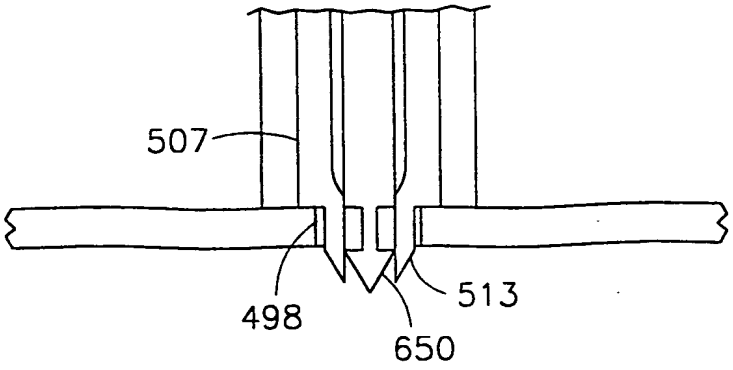

FIG.12R

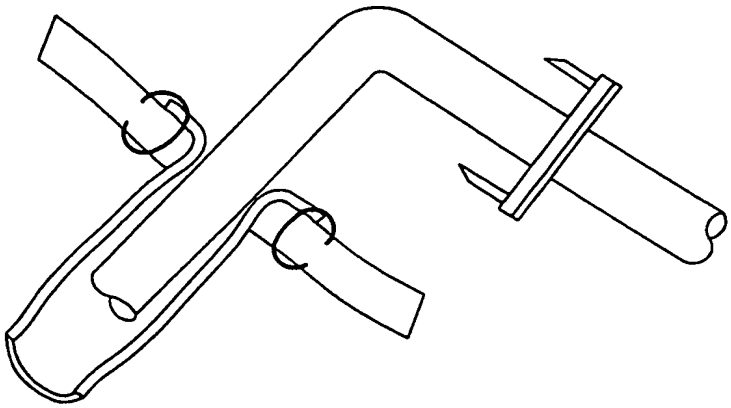

FIG.13C

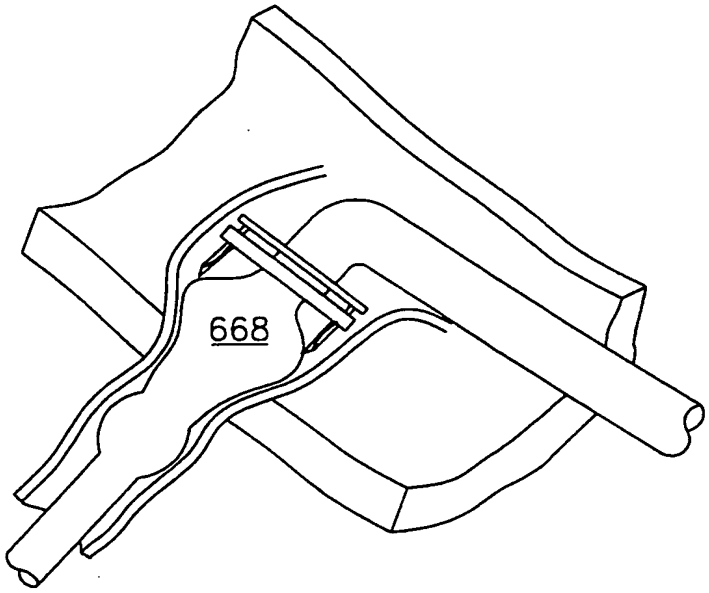

FIG.13D

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/IL99/00284

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed

☒ the description:
pages (See Attached), as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:
pages (See Attached), as originally filed
pages _____, as amended (together with any statement) under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the drawings:
pages (See Attached), as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the sequence listing part of the description:
pages (See Attached), as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages NONE

☒ the claims, Nos. NONE

☒ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/IL99/00284

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	1-158, 166-218	YES
	Claims	159-165	NO
Inventive Step (IS)	Claims	1-135, 143-158, 176-218	YES
	Claims	136-142, 159-175	NO
Industrial Applicability (IA)	Claims	1-218	YES
	Claims	NONE	NO

2. citations and explanations (Rule 70.7)

Claims 1-135, 143-158, and 176-218 meet the criteria set out in PCT Article 33(2)-(4) because the prior art does not teach or fairly suggest an anastomotic connector for attaching two blood vessels comprising a cylinder-like portion defining a lumen, having two ends and comprising an array of cells-elements; and a tissue engaging portion comprising at least one set of spikes comprising at least one spike arranged adjacent one of the two ends of said cylinder-like portion wherein said connector is adapted so the cylinder-like portion has no contact with blood flow when the connector is deployed; the prior art does not teach or fairly suggest a patch for sealing a hole in a blood vessel comprising a body which can be selectively collapsed or expanded, such that the patch fits inside a catheter having a diameter suitable for travel in said blood vessel; a plurality of tissue engaging elements on said patch; and a seal, wherein, when said device is expanded, placed over the hole, and the tissue engaging element engage said vessel, said seal seals said hole. The prior art also does not teach or fairly suggest a method of performing a bypass comprising the steps included in claims 182-215.

Claims 140-142 lack an inventive step under PCT Article 33(3) as being obvious over Kaster et al. (5,234,447). Kaster et al. disclose a graft having a side-to-end anastomic connector.
It would have been obvious to one having ordinary skill in the art at the time the invention was made to put Kaster et al.'s graft in a sterility-maintaining packaging in order to keep the graft sterile.

Claims 159-165 lack novelty under PCT Article 33(2) as being anticipated by Kaster et al. (5,234,447). Kaster et al. disclose a vessel holder, an expander (fig. 14-19, col. 6, lines 17-68).

Claims 166-175 lack an inventive step under PCT Article 33(3) (Continued on Supplemental Sheet.)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

I. BASIS OF REPORT:

This report has been drawn on the basis of the description,
page(s) 1-90, as originally filed.
page(s) NONE, filed with the demand.
and additional amendments:
NONE

This report has been drawn on the basis of the claims,
page(s) NONE, as originally filed.
page(s) NONE, as amended under Article 19.
page(s) NONE, filed with the demand.
and additional amendments:
Claim pages 91-114, filed with the letter of 21 September 2000.

This report has been drawn on the basis of the drawings,
page(s) 1-50, 52-63, 65-66, 68-69, as originally filed.
page(s) NONE, filed with the demand.
and additional amendments:
Pages 51, 64 and 67, filed with the letter of 21 September 2000

This report has been drawn on the basis of the sequence listing part of the description:
page(s) NONE, as originally filed.
pages(s) NONE, filed with the demand.
and additional amendments:
NONE

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):
as being obvious over Popov et al. in view of Shiber. Popov et al. disclose a tip mechanism for forming a hole in a blood vessel including all the limitations of the claims except for a presence of a motor coupled to said tip. Shiber discloses a cutting device comprising a motor coupled to a tip (fig. 1, col. 3, lines 58-68). It would have been obvious to one having ordinary skill in the art to use a motor for remotely controlling Popov et al.'s cutting tip.

Claims 136-139 lack an inventive step under PCT Article 33(3) as being obvious over Kaster et al. Kaster et al. disclose all the limitations of the claims except for a presence of an implantable device having a portion coated with a coagulation promoting material. It is a well known in the art to have an implantable device having at least a portion coated with a coagulation promoting material. It would have been obvious to one having ordinary skill in the art to coat a coagulation promoting material on a portion of Kaster's implantable device so that the coagulation promoting material coating would clot the blood and promote healing the surgical area.

---------- NEW CITATIONS ----------

US 5,041,082 A (Shiber) 20 Aug. 1991, see fig. 1, col. 3, lines 57-68
US 5,702,412 A (Popov et al.) 30 Dec. 1997, see fig. 3, col. 9 lines 1-68